92-1505

No. _____

Supreme Court, U.S.
FILED
MAR 16 1993
OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1992

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY;
ROBERT L. KENNEDY,

Respondents.

Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

California law requires that causation in a personal injury action be proven to a reasonable medical probability based upon competent expert testimony. The standard by which the trial court judges the admissibility of an expert's opinion is set forth in Federal Rule of Evidence 703, which has been interpreted to allow an expert to testify only to inferences and conclusions that are validated under the accepted standards and methods of the expert's particular field. The district court, in granting petitioner's motion for summary judgment, found that the testimony of respondent's expert failed to meet the above standards because the testimony was based upon *post hoc, ergo propter hoc* reasoning and was completely unsupported by any epidemiologic evidence. The panel for the Ninth Circuit initially affirmed the district court's opinion, but subsequently reversed upon rehearing.

1. Is an expert opinion based solely upon *post hoc, ergo propter hoc* reasoning, *and* unsupported by epidemiologic evidence, admissible to establish causation within a "reasonable medical probability" and defeat summary judgment under Federal Rule of Evidence 703?

2. Did the lower federal appellate court err in basing its reversal of the trial court's summary judgment ruling *solely* upon an affidavit stating a causation opinion "within a reasonable medical probability" based only upon *post hoc, ergo propter hoc* reasoning and unsupported by any epidemiologic evidence?

QUESTIONS PRESENTED – Continued

These issues are closely related to those now being addressed by the Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, No. 92-102.

RULE 28.1 LISTING

Petitioner Collagen Corporation has no parent companies, subsidiaries, or affiliates.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

RULE 28.1 LISTING iii

OPINIONS BELOW 1

JURISDICTION 1

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED 1

STATEMENT OF THE CASE 2

1. *Background* 2

2. *This Litigation* 3

REASONS FOR GRANTING THE WRIT 6

I. THIS COURT SHOULD RESOLVE THE PROTRACTED CIRCUIT DISPUTE OVER THE APPROPRIATE STANDARD FOR DETERMINING THE ADMISSIBILITY OF EXPERT TESTIMONY 6

II. THIS COURT SHOULD DECIDE WHETHER THE LOWER FEDERAL APPELLATE COURT ERRED IN BASING ITS REVERSAL OF THE TRIAL COURT'S ORDER GRANTING SUMMARY JUDGMENT, SOLELY UPON AN AFFIDAVIT STATING A CAUSATION OPINION "WITHIN A REASONABLE MEDICAL PROBABILITY" WHICH IS DEVOID OF ANY RATIONAL ANALYSIS AND UNSUPPORTED BY EPIDEMIOLOGIC EVIDENCE 10

A. "REASONABLE MEDICAL PROBABILITY" 11

B. "SCIENTIFIC METHODOLOGY" 11

TABLE OF CONTENTS – Continued

Page

C. "SUFFICIENT FOUNDATION" 15

D. SPINDLER'S AFFIDAVIT FAILS TO DEMONSTRATE A SCIENTIFICALLY ACCEPTED METHOD FOR REACHING ITS CONCLUSION 18

1. Temporal Relationship 19

2. Antibodies 20

III. CONCLUSION 22

TABLE OF AUTHORITIES

Page

Federal Cases

American School of Magnetic Healing v. McAnnulty, 187 U.S. 94 (1902) 12, 15

Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir. 1989) 8, 17, 18

Christophersen v. Allied-Signal Corp., 939 F.2d 1106 (5th Cir. 1991) 9

Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991), cert. granted, 61 U.S.L.W. 3061 (U.S. October 13, 1992) (No. 92-102) 7, 9

Daubert v. Merrell Dow Pharmaceuticals, Inc., 727 F.Supp. 570 (S.D. Cal. 1989), *aff'd*, 951 F.2d 1128 (9th Cir. 1991) 8, 15

Deluca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir. 1990) 9

Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir. 1984) 12, 14

Hardt v. Heidweyer, 152 U.S. 547 (1894) 19

Hull v. Merrell Dow Pharmaceuticals, Inc., 700 F.Supp. 28 (S.D. Fla. 1988) 17

In re Agent Orange Product Liability Lit., 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987) 18

In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation, 624 F.Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989) 17

TABLE OF AUTHORITIES – Continued

Page

Lynch v. Merrell-National Labs, 830 F.2d 1190 (1st Cir. 1987) 8, 17

Mid-State Fertilizer Co. v. Exchange National Bank of Chicago, 877 F.2d 1333 (7th Cir. 1989) 12

Pharmaceutical Manufacturers Association v. Richardson, 318 F.Supp. 301 (D.Del. 1970) 13

Railway Labor Executives Ass'n v. Dole, 760 F.2d 1021 (9th Cir. 1985) 19

Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988) 8, 16, 17

Richardson v. Richardson-Merrell, Inc., 649 F.Supp. 799 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988) 20

Thomas v. Hoffman-La Roche, Inc., 949 F.2d 806 (5th Cir. 1992) 14

Thomas v. Hoffman-La Roche, Inc., 731 F.Supp. 224 (N.D. Miss. 1989), *aff'd*, 949 F.2d 806 (5th Cir. 1992) 17

Thompson v. Merrell Dow Pharmaceuticals, Inc., 229 N.J. Super. 230, 551 A.2d 177 (1988) 18

United States Mutual Acc. Ass'n v. Barry, 131 U.S. 100 (1889) 19

United States v. Linton, 655 F.2d 930 (9th Cir. 1980) 20

United States v. Robinson, 644 F.2d 1270 (9th Cir. 1981) 19

United States v. Solomon, 753 F.2d 1522 (9th Cir. 1985) 16

TABLE OF AUTHORITIES – Continued

Page

Weinberger v. Hynson, Westcott and Dunning, Inc., 412 U.S. 609 (1973) 13

Wilkins v. University of Houston, 654 F.2d 388 (5th Cir. 1981) 20

STATE CASES

People v. Abraham, 185 Cal.App.3d 1221, 230 Cal. Rptr. 325 (1986) 20

People v. Benson, 52 Cal.3d 754, 802 P.2d 330 (1990) 19

Thompson v. Merrell Dow Pharmaceuticals, Inc., 229 N.J. Super. 230, 551 A.2d 177 (1988) 18

FEDERAL STATUTES & RULES

21 Code of Federal Regulations, § 314.126 (1990) .13, 14

Federal Food, Drug and Cosmetic Act, 21 United States Code § 355(d) (1991) 13

Federal Rule of Evidence 703 ..... 15, 16, 18

OTHER AUTHORITIES

Guidelines for Good Epidemiology Practices for Occupational and Environmental Research, 33 Journal of Occupational Medicine 1221 (December 1991) 14

Black's Law Dictionary (6th ed. 1991) 12

Garner, *A Dictionary of Modern Legal Usage* (Oxford University Press 1987) 11

Stites and Terr, *Immunology* (7th ed. 1991) 20, 21

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit, reversing the District Court's grant of summary judgment for petitioners, is unreported and is reprinted in the Appendix hereto, at p. 1a (references to the Appendix bound with this petition are styled "___a.") The opinion of the United States Court of Appeals for the Ninth Circuit, affirming the District Court's grant of summary judgment for petitioners, is unreported and is reprinted at p. 11a. The memorandum decision and order of the United States District Court for the Northern District of California is unreported and is reprinted at p. 13a.

JURISDICTION

The decision of the Court of Appeals, reversing the District Court, was announced on September 8, 1992. A timely petition for rehearing and suggestion for rehearing *en banc* was denied on December 16, 1992. See p. 22a. The jurisdiction of this court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

The text of the statutes are printed in the appendix, beginning on p. 23a.

STATEMENT OF THE CASE

Charlotte Kennedy claims to have developed systemic lupus erythematosus ("SLE") as a result of treatment with Zyderm(R) Collagen Implant ("Zyderm"), a prescription medical device manufactured by Collagen Corporation. Petitioner moved for summary judgment after discovery revealed that none of Kennedy's treating physicians or experts would testify that Zyderm caused Kennedy's condition. Unable to oppose the motion with any evidence produced during discovery, respondents' obtained a "last minute" affidavit in which a physician stated a causation opinion. His opinion, based solely upon *post hoc, ergo propter hoc* reasoning, was utterly devoid of any rational analysis or any support from the scientific literature. The district court below concluded, as did the Ninth Circuit initially, that petitioner was entitled to summary judgment on the ground that respondents had failed to come forward with sufficient evidence to create a genuine issue of fact material to their claim that Zyderm caused Kennedy's condition. That conclusion was reversed upon rehearing by the Ninth Circuit.

1. *Background.* This is a product liability action commenced in the Northern District of California on February 23, 1988. The jurisdiction of the district court was invoked under 28 U.S.C. § 1332 because of diversity of citizenship; the plaintiff is a citizen of Georgia and the defendant is a citizen of Delaware and California.

Zyderm is a Class III prescription medical device which is used by physicians in the treatment of soft tissue defects of the skin, such as scars or wrinkles, caused by disease, trauma, congenital defect or aging. Zyderm is

composed of purified bovine dermal collagen dispersed in a phosphate-buffered saline solution. It is injected, by or under the direction of a physician, into the dermal layer of skin.

2. *This Litigation*. In the 15 months following the filing of plaintiff's complaint, the parties conducted extensive discovery. Collagen Corporation deposed, among others, more than a dozen of Charlotte Kennedy's health care providers, including dermatologists, plastic surgeons, internists, rheumatologists, psychiatrists and psychologists. In deposition, none of plaintiff's experts were willing to testify to a cause and effect relationship between Charlotte Kennedy's treatment with Zyderm and her alleged injury. On the basis of plaintiff's expert testimony, Collagen Corporation moved for summary judgment. In opposition to the motion, plaintiffs relied on the deposition testimony of Dr. Denny Tuffanelli and the affidavit of Dr. Joseph Spindler.

At his deposition, Dr. Tuffanelli could only postulate that it was *possible* that Zyderm caused Charlotte Kennedy's alleged injury. He testified:

> The *speculation* is that if something such as collagen can turn on an autoimmune response, then the type of autoimmune response, again, would be determined in all likelihood, by the patient's genetic makeup.
>
> *I don't know* if it causes an autoimmune response at this time. (Emphasis supplied.)

Dr. Tuffanelli also testified that an expert would require epidemiologic studies, animal studies and case reports to reach the conclusion that there was a cause and

effect relationship between treatment with Zyderm and the development of SLE, but admitted that such evidence simply did not exist. Dr. Tuffanelli conceded that he had no basis for his opinion, other than his belief that it was so, but testified, nonetheless:

> [U]ntil I see some good published data in that area, I will remain unconvinced that it is not causing these diseases.

Although Dr. Spindler was willing to assert that his opinion was "based on reasonable medical probability," close scrutiny of his affidavit revealed that his opinion was based on nothing more than an alleged temporal association between Charlotte Kennedy's treatment with Zyderm and her alleged development of an unspecified "systemic immunologic injury." Dr. Spindler stated:

> *Prior to her injections* . . . [plaintiff's] records and history reflect an absence of . . . any immunological condition. *Her clinical course*, however, dramatically and *temporally deteriorated following her third injection*. . . .
>
> Mrs. Kennedy's medical history, records and current laboratory results are consistent *with a temporal relationship* between her injections and her medical condition. . . .
>
> . . . *[W]ith the temporal relationship, it appears the injections acted as a trigger* in the development and progression of her evolving systemic-immune condition and disorders. (Emphasis supplied.)

(pp. 20-21a.)

The strongest statement Dr. Spindler was able to offer regarding the diagnostic and probative value of plaintiff's laboratory results was equally deficient. He could only state:

> The existence of an anti-histone antibody *is suspect* that her immune system was triggered by an external source, *which could have been* . . . the injections. . . .
>
> [C]urrent laboratory test results for her, . . . reveal a change in her ANA, and in the existence of anticentromere antibody, *previously not present*. (Emphasis supplied.)

(pp. 20-21a.)

On December 19, 1990, the District Court granted Collagen Corporation's motion for summary judgment. In its Order, the District Court addressed the sufficiency of plaintiff's evidence of causation and concluded:

> [Dr. Tuffanelli] did not express an opinion on the probability of causation, and he indicated that causation theories are currently based upon speculation. This is not evidence sufficient to meet the standard of Federal Rule of Evidence 703, and does not meet the standard of proof of medical causation required by California law.
>
> [E]ven Dr. Spindler's affidavit does not sustain plaintiff's burden of establishing a genuine issue of material fact and causation. His opinion is based primarily on the temporal relationship between plaintiff's use of the ZCI in the development of her disease (*post hoc, ergo propter hoc*). The most he can say is that the ZCI injections were "suspect," and that her condition "could have been" caused by ZCI. . . . Therefore, the

> court must conclude that even Dr. Spindler's affidavit does not create the genuine issue of material fact on medical causation necessary to defeat summary judgment.

(pp. 16-17a.)

On June 8, 1992, a panel of the Court affirmed without dissent. Discussing the affidavit (and statements by plaintiff's experts in discovery), the court described the evidence as "either speculative, highly equivocal, or both." (pp. 11-12a.) The evidence "thus provided an insufficient basis for a reasonable jury to find causation." (p. 12a.)

On September 8, 1992, the court reversed itself. Although neither the facts nor the law had changed in the interim, two members of the panel decided that the affidavit "read in its entirety, clearly stated [the physician's] opinion of reasonable medical probability," and therefore concluded the trial court wrongly blocked plaintiff from presenting their case to a jury. (p. 5a.) Circuit Judge Kozinski dissented: "Dr. Spindler's affidavit is simply too indefinite to establish a 'reasonable medical probability' that Kennedy's disorder is any way linked with defendant's [product]; it is rank speculation." (p. 10a.)

REASONS FOR GRANTING THE WRIT

I. THIS COURT SHOULD RESOLVE THE PROTRACTED CIRCUIT DISPUTE OVER THE APPROPRIATE STANDARD FOR DETERMINING THE ADMISSIBILITY OF EXPERT TESTIMONY

The appropriate standard for determining the admissibility of expert testimony to establish causation is an

issue that has long divided the circuits, including the court below. This Court recently agreed to examine the conflict and address the issue in a case decided by the Court of Appeals for the Ninth Circuit in *Daubert v. Merrell Dow Pharmaceuticals*, 951 F.2d 1128 (9th Cir. 1991), *cert. granted*, 61 U.S.L.W. 3061 (U.S. October 13, 1992) (No. 92-102). In *Daubert*, faced with the identical task of the court below, the district court scrutinized the proposed testimony of eight expert witnesses relied upon by plaintiffs to oppose defendant Merrell Dow's motion for summary judgment in which Merrell Dow argued that plaintiffs lacked sufficient evidence to raise a triable issue regarding whether Bendectin had caused birth defects in the plaintiffs. In *Daubert*, contrary to this case, the plaintiff did present some epidemiologic evidence, however, the court found that the evidence presented lacked the sufficient foundation necessary under Fed. R. Evid. 703. Summarizing its holding, the district court, reasoned:

> The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area. *Accordingly, expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under FRE 703.* Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is generally based upon in vitro studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of

> their opinion (citing *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 1511 (1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989); *Lynch v. Merrell-National Labs*, 830 F.2d 1190 (1st Cir. 1987.) (Emphasis supplied.)

Daubert, 727 F.Supp. 570, 575 (S.D. Cal. 1989), *aff'd, supra*, 951 F.2d 1128 (9th Cir. 1991).

The district court added:

> The defendants have introduced evidence that no epidemiological study ever performed has concluded that the use of Bendectin by pregnant women has a statistically significant association to birth defects in those women's children. . . . The plaintiffs argue that the absence of statistically significant epidemiological studies does not disprove the fact that Bendectin causes limb reduction defects. However, this argument directly contradicts the holdings of *Brock*, *Richardson* and *Lynch*. *The plaintiffs have the burden of proof, and they must come forward with statistically significant epidemiological evidence.* (Emphasis supplied.)

Id.

The Court of Appeals for the Ninth Circuit affirmed.

In stark contrast to the *Daubert* holding, when asked to scrutinize the affidavit of one expert witness, relied upon to oppose petitioner's motion for summary judgment, the Ninth Circuit below reversed on the ground that Spindler's affidavit read as a whole states a causation opinion to a "reasonable medical probability"

despite the fact that the expert opinion lacked *any* application of scientific method or *any* support from the scientific or medical literature.

The direct intracircuit conflict between the pending *Daubert* decision currently before this Court and the decision below is a symptom of the contagious conflict spreading among the other circuits. In *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991), *cert. denied*, 112 S.Ct 1280 (White, J. dissenting), Justice White observed that the appropriate standard for determining the admissibility of expert testimony is "an important and recurring issue" that "has long divided federal courts, and here deeply divided the Court of Appeals for the Fifth Circuit, sitting en banc." *See also, Deluca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), in which the Third Circuit specifically rejected the *Frye/Solomon* "generally accepted" standard in ruling on the admissibility of expert testimony. The Ninth Circuit in *Daubert* declined to follow the *Deluca* holding, because it was contrary to established precedent.

This case and *Daubert* present this Court with an opportunity to issue a united edict concerning the proper standard a court must apply in determining the sufficiency of expert testimony in establishing causation and, once and for all, resolve the confusion arising from the myriad inconsistent decisions rendered by courts which have examined similar issues.

II. THIS COURT SHOULD DECIDE WHETHER THE LOWER FEDERAL APPELLATE COURT ERRED IN BASING ITS REVERSAL OF THE TRIAL COURT'S ORDER GRANTING SUMMARY JUDGMENT, SOLELY UPON AN AFFIDAVIT STATING A CAUSATION OPINION "WITHIN A REASONABLE MEDICAL PROBABILITY" WHICH IS DEVOID OF ANY RATIONAL ANALYSIS AND UNSUPPORTED BY EPIDEMIOLOGIC EVIDENCE

The first substantive paragraph of Spindler's affidavit[1] says that (1) Kennedy's pre-Zyderm medical records do not indicate that she had SLE, (2) her post-Zyderm records show an SLE diagnosis and "anti-histone antibody," and (3) the "existence of anti-histone antibody is *suspect* [sic] that her immune system was triggered by an external source, which *could have been* [Zyderm]." (p. 20a.)

The next paragraph states that (1) Kennedy's "medical history, records and current laboratory results are *consistent with a temporal relationship*" between Zyderm and SLE, and (2) laboratory results "reveal a change in her ANA" and "the existence of anticentromere antibody." (p. 21a, emphasis supplied.)

The third and last paragraph says, "[b]ased on reasonable medical probability," that Kennedy had an immunologic reaction to Zyderm which was a "substantial

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[1] The petitioner restricts examination of the sufficiency of the respondent's expert testimony to an analysis of Dr. Spindler's affidavit because, in reversing its previous ruling, the Ninth Circuit limited its analysis to a review of Dr. Spindler's affidavit only, implying that Dr. Tuffanelli's testimony was insufficient.

factor" in causing a "changing immunological picture." (p. 21a.) The only stated basis for this conclusion was "the temporal relationship." (p. 21a.)

Thus, Spindler's causation opinion had two bases: (1) the presence of "anti-histone antibody" and "anti centromere antibody," and a "change" in "ANA"; and (2) that Kennedy became ill at some time after receiving Zyderm.

A. "REASONABLE MEDICAL PROBABILITY"

As the Ninth Circuit acknowledged in both of its decisions, California law requires a plaintiff *to establish* causation "within a reasonable medical probability." It is not enough for Spindler to *say* "reasonable medical probability," he must *show why* it is more probable than not that Zyderm caused Kennedy's SLE.

B. "SCIENTIFIC METHODOLOGY"

The Ninth Circuit concluded that summary judgment was improper because Collagen Corporation did not dispute that Spindler's affidavit was based on accepted "methodology." (This was wrong – Collagen Corporation vehemently disputes that the affidavit's conclusion was based on *any* application of the scientific method, much less upon accepted "methodology.")

The use of "methodology" in this context is a misnomer. (*See* Garner, *A Dictionary of Modern Legal Usage*

(Oxford University Press 1987).)[2] The question is whether Spindler's affidavit demonstrates that the opinion expressed was reached by application of accepted scientific method.

"Method" is neither data nor opinion. It is the *means* by which an opinion is reached. *Black's Law Dictionary* (6th ed. 1991). An expert's method must be more than data – it must include a rationale for getting from the data to the opinion.

> [A]ffidavits opposing motions for summary judgment "shall set forth facts" and by implication in the case of experts (who are not "fact witnesses") a process of reasoning beginning from a firm foundation. Expertise is a rational process and a rational process implies expressed reasons for judgment.

Mid-State Fertilizer v. Exchange National Bank, 877 F.2d 1333, 1339 (7th Cir. 1989) (citation and internal quotations omitted).

There is a scientific method for determining the effects of substances on human health. Ninety years ago, this Court ruled that the government was powerless to prevent quack medical treatments. *American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94 (1902). Thirty years ago, however, Congress amended the Federal Food,

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[2] The "methodology" standard was originated by *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), *cert. denied*, 469 U.S. 1062. *Ferebee* gave the following examples of what it termed "well-founded methodologies": "use of tissue samples, standard tests, and patient examination." *Id.* at 1536. Obviously, these are examples of data, not of "methodology" in the commonly accepted sense of that term.

Drug, and Cosmetic Act to require proof of a medication's efficacy prior to marketing. Testifying in support of the amendment, Dr. Charles May of the New York University School of Medicine pointed out the "fallacy" that "a collection of impressions" will furnish the truth:

> This approach did not prevent doctors from having unbounded faith in the curative powers of leeches for hundreds of years before scientific evaluation became the preferred means of judging efficacy of therapy.

Pharmaceutical Manufacturers Association v. Richardson, 318 F.Supp. 301, 307 (D.Del. 1970). Based on the testimony of Dr. May and other physicians that mere anecdotal evidence is insufficient and "the impressions or beliefs of physicians, no matter how fervently held, are treacherous," the Act was amended to require manufacturers to provide the FDA, at the outset, with "substantial evidence" of drug efficacy. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 617-19 (1973).

"Substantial evidence" is defined in the Act as requiring "evidence of adequate and well-controlled investigations, including clinical investigations." Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(d) (1991). The implementing regulation sets forth in detail the characteristics of the required clinical trials, including a requirement of statistical significance, and the assignment of subjects and controls to test groups in such a way as to minimize bias and to control for confounding factors. 21 Code of Federal Regulations § 314.126 (1990). The regulation states that "[i]solated case reports, random

experience, and reports lacking the details which permit scientific evaluation will not be considered." (*Ibid.*)[3]

Randomized trials are neither feasible nor ethical for determining whether substances cause disease. Nevertheless, the science of epidemiology has developed techniques which parallel those of randomized trials when randomization cannot be used. *See Guidelines for Good Epidemiology Practices for Occupational and Environmental Research,* 33 Journal of Occupational Medicine 1221 (December 1991).

The standard objection to use of the scientific method in tort litigation is that it requires a statistically significant number of injuries before sound conclusions can be drawn. *Ferebee,* 736 F.2d at 1536. However, the alternative of rejecting the scientific method and allowing a toxic tort case to go forward when human data to support a conclusion of toxicity are insufficient or non-existent has its own undesirable consequences, which the courts have tended to ignore. Defense and settlement dollars paid in quack medicine and "junk science" cases as the result of judicial rejection of the scientific method do not fall from heaven; rather they reduce the funds available to develop beneficial products, to conduct voluntary research on the effects of chemicals, to employ workers, to pay medical premiums, and to pay taxes and contributions which fund socially desirable goals such as legitimate medical treatment and research.

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[3] *See Thomas v. Hoffman-La Roche, Inc.*, 949 F.2d 806, 815 (5th Cir. 1992), *cert. denied*, 112 S.Ct. 2304, for an example of how anecdotal reports can be misleading.

The scientific method is not an ad hoc creation of either the plaintiffs' bar or industry, but rather has been elaborated over many years by the scientific community and has been for some decades now the only accepted method for determining actual (as opposed to feared) effects of chemicals in humans. The courts' obligation to reject proof based on possibilities rather than probabilities, their obligation of neutrality, and their lack of independent expertise have led to a long-standing preference for established and objective modes of proof when they are available.

These values, as well as considerations of judicial and economic efficiency, argue strongly in favor of judicial acceptance of the scientific method as the sole standard for determining admissibility of expert testimony, and for rejection of a protracted, contentious, expensive, and futile search by each court in the land for alternative "methodologies" of proving causation without basis in sound epidemiology.

C. "SUFFICIENT FOUNDATION"

"[E]xpert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under FRE 703." *Daubert*, 727 F.Supp. at 575.

In making a foundational inquiry with respect to Spindler's affidavit, the district court below examined

not only the standard of proof of medical causation required by California law but also examined the sufficiency of Spindler's affidavit pursuant to Federal Rule of Evidence 703 which lays the foundation for consideration of what constitutes adequate expert testimony.[4] That rule provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

As the *Richardson* court observed,

> Rule 703 "was intended to broaden the acceptable bases of expert opinion, but it was not intended . . . to make summary judgment impossible whenever a party has produced an expert to support its position;" rather, we emphasize, "the grounds relied upon by an expert must be 'a type reasonably relied upon by experts in the particular field.'" Similarly, it has been held that a scientific causation issue may be removed from the jury on a motion for a directed verdict

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[4] Circuit courts, in examining the foundational approach to expert testimony have either focused on Rule 702 (*see, United States v. Solomon*, 753 F.2d 1522 (9th Cir. 1985)) or Rule 703 which several other courts have relied on in examining the foundational approach to expert testimony. *See e.g., Richardson*, 857 F.2d at 830-31.

> if the evidence only "provides a 'mere possibility' yet not a 'probability' of the proof."

Richardson, 857 F.2d at 829.

Courts are beginning to embrace the principle that plaintiffs in cases such as this may not get to a jury in the absence of sound and statistically significant epidemiological proof that the substance causes the condition in question. In *Brock v. Merrell Dow Pharmaceuticals, Inc., supra*, the court found plaintiffs' "failure to present statistically significant epidemiological proof . . . fatal to their case." *Brock*, 874 F.2d at 313. "[S]peculation unconfirmed by epidemiological proof cannot form the basis for causation in a court of law." *Id.* In *Thomas v. Hoffman-La Roche*, 731 F.Supp. 224 (N.D. Miss. 1989), *aff'd, supra*, 949 F.2d 806, plaintiff claimed an acne medication had caused seizures. The trial court granted judgment n.o.v. after the jury returned a substantial verdict for the plaintiff, finding that the causation opinion given by plaintiff's treating neurologists lacked an adequate basis. *Thomas* construed *Brock* as holding that "a plaintiff in a prescription drug product liability case must present statistically significant epidemiological proof." *Id.* at 228. The court rejected the argument that *Brock*'s rationale applies only in cases, like those involving Bendectin, where numerous epidemiological studies have beer. conducted. *Id.* at 230.[5]

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[5] *See also, Richardson*, 857 F.2d at 829-831; *Lynch*, 830 F.2d 1190, 1196-1197 (1st Cir. 1987); *Hull v. Merrell Dow Pharmaceuticals, Inc.*, 700 F.Supp. 28 (S.D. Fla. 1988); *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F.Supp. 1212

As the case law's application of Federal Rule of Evidence 703 demonstrates, expert opinion, wholly unsupported by the epidemiologic evidence, is entirely insufficient to bolster a causation opinion.

D. SPINDLER'S AFFIDAVIT FAILS TO DEMONSTRATE A SCIENTIFICALLY ACCEPTED METHOD FOR REACHING ITS CONCLUSION

The Ninth Circuit reversed on the ground that Spindler's affidavit, read as a whole, states a causation opinion to a "reasonable medical probability." This says nothing more, really, than that Spindler employs the words "reasonable medical probability." However, in cases like this, courts must "critically evaluate the *reasoning process by which the experts connect data to their conclusions* in order for courts to consistently and rationally resolve the disputes before them." *Brock*, 874 F.2d at 310, emphasis supplied.

As the dissent correctly points out, Spindler's affidavit is *nothing but* raw data and an ultimate conclusion. There *is no* reasoning process linking the data to the conclusion. There is no method or "methodology." It is nothing more than an anecdotal report of one patient and

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(S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989); *In re Agent Orange Product Liability Lit.*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987); *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 229 N.J. Super. 230, 551 A.2d 177 (1988).

the observation of one physician. There is no epidemiological support whatsoever. There is no reference to any medical or scientific literature. There is no suggestion that anyone (much less a medical consensus) other than Spindler believes Zyderm causes SLE in general or caused Kennedy's SLE. (Indeed, the "consensus" expressed by Kennedy's own experts is to the contrary. Not one could or would testify that Zyderm caused her condition.)

As outlined earlier, Spindler's opinion has two bases: (1) a "temporal relationship" (that is, Kennedy became ill at some point after receiving Zyderm), and (2) the presence of certain antibodies in Kennedy's serum, which leads Spindler to "suspect" that Zyderm "could have been" the cause of Kennedy's SLE.

1. Temporal Relationship

This Court has long agreed that temporal reasoning is insufficient to establish causation. *See, Hardt v. Heidweyer*, 152 U.S. 547, 558 (1894) ("*Post hoc propter hoc* is not, however, sufficient, and the rule of causation implies some other sequence than that of time."); *United States Mutual Acc. Ass'n v. Barry*, 131 U.S. 100 (1889). The California Supreme Court has recently reaffirmed that "temporal priority does not establish causal force: it is a logical fallacy to reason *post hoc ergo propter hoc*." *People v. Benson*, 52 Cal.3d 754, 781, 802 P.2d 330, 345 (1990), *cert. denied*, 112 S.Ct. 336 (1991). The Ninth Circuit has repeatedly agreed, calling such reasoning fallacious. *See Railway Labor Executives Ass'n v. Dole*, 760 F.2d 1021, 1023 (9th Cir. 1985); *United States v. Robinson*, 644 F.2d 1270, 1273 (9th

Cir. 1981); *United States v. Linton*, 655 F.2d 930, 932 (9th Cir. 1980), *cert. denied*, 451 U.S. 912 (1981). *See also People v. Abraham*, 185 Cal.App.3d 1221, 1231, 230 Cal. Rptr. 325, 331 (1986) (Poche, P.J., concurring) ("at most defendant has proved a temporal sequence. . . . That is insufficient. It always has been: after this, therefore because of this, is a fallacy so old it has a Latin name: *post hoc, ergo propter hoc.*")

The fallacy of inferring causation from a temporal sequence has been recognized in cases such as this. *See Richardson*, 649 F.Supp. 799, 803, *aff'd*, 857 F.2d 823 (D.C. Cir. 1988). Every illness follows a multitude of exposures and events. In the absence of more compelling scientific proof, causation cannot be inferred.

> [T]he day is long past . . . when we proceed with any confidence toward broad conclusions from crude and incomplete statistics. That everyone who has eaten bread has died may tell us something about bread, but not very much.

Wilkins v. University of Houston, 654 F.2d 388, 410 (5th Cir. 1981). If temporal relationship is sufficient to support a causation opinion, then the requirement of generally accepted scientific method is meaningless.

2. Antibodies

SLE "is now known to be a chronic systemic inflammatory disease that follows a course of alternating exacerbations and remissions. Multiple organ system involvement characteristically occurs during periods of disease activity. The cause is not known." Stites and Terr, *Immunology* 438 (7th ed. 1991). Patients who have SLE produce a number of antinuclear antibodies. *Id.* at

438-439. The term "antinuclear antibodies," or "ANA," refers to a large number of antibodies, including anti-histone and anticentromere antibodies. *Id.*, Table 36-1.

Spindler examined Kennedy after she had developed SLE. He says she had a "positive ANA," "anti-histone antibody" and "anticentromere antibody." But this is nothing more than raw descriptive data. To say that a patient has a "positive ANA" is merely to say the patient has been found to exhibit a symptom common to patients with SLE. The presence of anti-nuclear antibodies is a "major immunologic feature" of SLE. *Id.* at 438. Moreover, the presence of "numerous other autoantibodies," including anti-histone and anticentromere antibodies, is another "major immunologic feature" of SLE. *Id.* at 438-441. A positive ANA, and the presence of anti-histone and anti-centromere antibodies, are merely part of the "immunologic diagnosis" of SLE. *Id.* at 441. To say that Zyderm causes SLE because Kennedy was exposed to the product, developed SLE, and tested positive for antibodies is akin to saying that aspirin causes AIDS because a patient took aspirin, developed AIDS, and tested positive for HIV.

As the Ninth Circuit dissent correctly observes, Spindler does not "explain the meaning of 'ANA' or 'anti-centromere antibody,' nor does he intimate what either of those has to do with plaintiff's case against the defendant." Instead, the presence of antibodies simply leads Spindler to "suspect" that Kennedy's SLE was "triggered by an external source" which "could have been" Zyderm. Perhaps it is the utter lack of any scientific support that led Spindler to couch his opinion in such tentative and speculative terms. Under substantive California law and

the Federal Rules of Evidence, this sort of speculation is facially insufficient to support a finding of causation.

III. CONCLUSION

For all these reasons, certiorari should be granted.

Respectfully submitted,

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Dated: March 16, 1993

APPENDIX

NOT FOR PUBLICATION

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CHARLOTTE KENNEDY and ROBERT KENNEDY, Plaintiffs-Appellants, v. COLLAGEN CORPORATION, Defendant-Appellee.	NO. 91-15597 D.C. NO. CV-89-02331-CAL **MEMORANDUM***
	(Filed Sept. 8, 1992)

Appeal from the United States District Court
for the Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted May 15, 1992
San Francisco, California

BEFORE: FERGUSON, REINHARDT, and KOZINSKI, Circuit Judges.

This is a products liability case which ended with the granting of summary judgment for the defendant. We reverse.

The action arises from Charlotte Kennedy's treatment with Zyderm[R] Collagen Implant ("Zyderm"), a prescription medical product manufactured by defendant Collagen Corporation ("Collagen"). Zyderm is injected by a doctor into facial wrinkles for a smoother appearance.

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* This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

Kennedy claims to have developed systemic lupus erythematosus, an automimmune [sic] disease, as a result of this treatment.

Collagen filed a motion for summary judgment on the ground that the plaintiffs had failed to produce any evidence establishing a prima facie case of causation.

At the hearing on the motion, the plaintiffs submitted an affidavit executed by Dr. Joseph Spindler on the issue of causation. The district court concluded that neither the testimony of the plaintiffs' designated expert witnesses nor Dr. Spindler's affidavit raised a genuine issue of material fact on the issue of causation. In addition, the court denied the plaintiffs' motion to designate additional experts, including Dr. Spindler, because the motion was untimely.

The plaintiffs subsequently filed a motion for a new trial, which the court also denied.

We reverse. Dr. Spindler's affidavit established the existence of a genuine issue of material fact regarding causation and was sufficient to preclude summary judgment.

DISCUSSION

We review the district court's grant of summary judgment de novo. *State Farm Fire & Casualty Co. v. Martin*, 872 F.2d 319, 320 (9th Cir. 1989). We must determine, viewing the evidence in the light most favorable to the nonmoving party, whether there are any genuine issues of material fact and whether the district court correctly applied the

relevant substantive law. *Tzung v. State Farm Fire & Casualty Co.*, 873 F.2d 1338, 1339-40 (9th Cir. 1989).

In moving for summary judgment, the defendant did not offer any testimony or affidavits of its own witnesses. Instead, it relied on the deposition testimony of the plaintiffs' experts, excluding of course Dr. Spindler's affidavit.

We confine our study of the record to Dr. Spindler's affidavit and do not determine the sufficiency of the deposition testimony of the plaintiffs' other medical experts.

Under California law, the Kennedys were required to prove causation "within a reasonable medical probability based upon competent expert testimony." *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal. App. 3d 396, 402 (1985). Dr. Spindler's affidavit was such testimony and was sufficient to establish the existence of a genuine issue of material fact regarding causation. Dr. Spindler affirmed that "[b]ased on reasonable medical probability," the Zyderm injections caused Charlotte Kennedy's systemic immunological injuries. Dr. Spindler based his opinion on his examination of Kennedy; review of her medical history and records; numerous laboratory tests of Kennedy which showed a positive ANA, anti-histone antibody, and anticentromere antibody; and the temporal relationship between the injections and her condition. Accepted on its own terms, the affidavit demonstrated a "reasonable medical probability" that the defendant's conduct caused Kennedy's injuries.

The defendant contends that Dr. Spindler's use of language such as "suspect" and "could have been" rendered the affidavit insufficient to establish a "reasonable medical probability." We disagree.

California courts have held that words such as "speculative" and "conjecture" do not render a doctor's testimony speculative if, taken as a whole, the testimony states the doctor's opinion of reasonable medical probability. *See Cullum v. Seifer*, 1 Cal. App. 3d 20, 26 (1969); *Gay v. Workers' Compensation Appeals Bd.*, 96 Cal. App. 3d 555, 564 (1979). In *Gay*, the plaintiff appealed a finding of the Workers' Compensation Appeals Board that apportioned 50 percent of his psychiatric disability as nonindustrial. The plaintiff attacked the opinion of the psychiatrist who had recommended apportionment and argued, *inter alia*, that the opinion could not support apportionment because it included the statement, "Whether any of the symptoms preexisted [the patient's] current employment is speculative since the patient denies it." The plaintiff contended that this statement showed that the psychiatrist was improperly "speculating" about apportionment. The court disagreed, stating:

> In evaluating a medical report, isolated statements may be misleading. Intellectual candor of a physician may lead to single statements which, when isolated, may be misunderstood. In evaluating the evidentiary value of medical evidence, a physician's report and testimony must be considered as a whole rather than in segregated parts. Thus, the physician's entire report and testimony when considered a [sic] a whole,

> must demonstrate that, based upon reasonable medical probability, there is a legal basis for apportionment.

96 Cal. App. 3d at 564 (citations omitted).

In *Cullum*, a malpractice case, the court reviewed the testimony of an expert witness, a doctor, who testified on the issue of proximate cause. The court examined the totality of the doctor's testimony on the issue and concluded that even though the witness referred at one point to "conjecture," the testimony as a whole stated the doctor's opinion of reasonable medical probability. The court explained:

> The isolated characterization of 'conjecture' must be weighed as to its true meaning and significance in the light of the testimony which preceded it. . . . [T]he main object is not to draw fine distinctions based upon accurate definitions or words, but to ascertain the real idea expressed."

1 Cal. App. 3d at 26 (citations and internal quotation marks omitted). Here, Dr. Spindler's affidavit, read in its entirety, clearly stated his opinion of reasonable medical probability.

A jury was entitled to hear Dr. Spindler's testimony. *See Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1535 (D.C. Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984). In *Ferebee*, where both sides presented expert opinion testimony on the issue of whether paraquat poisoning caused the plaintiff's pulmonary fibrosis, the D.C. Circuit held that the jury was entitled to decide the victor in the battle of experts. *Id.* The court distinguished between the standard for the admission of evidence based on novel scientific

techniques or methodologies, where "the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field," and the standard for "the admission of scientific opinion testimony that, while controversial in its conclusions, is based on well-founded methodologies." *Id* (citations and internal quotation marks omitted). The court stated further:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors *could* conclude from the expert testimony that paraquat more likely than not caused [the plaintiff's] injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. That [the plaintiff's] case may have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly well qualified in their fields, should not have been admitted.

Id. at 1535-36 (emphasis in original).

Here, the reliability of Dr. Spindler's methodology is not disputed. The district court was inaccurate in believing that Dr. Spindler's opinion was based primarily on the temporal relationship between the Zyderm injections and Kennedy's injuries and was not based on "any other laboratory tests of plaintiff, epidemiological evidence, or toxicological evidence." Furthermore, the court was not presented with any facts demonstrating that Dr. Spindler's methodology differed from procedures generally accepted by authorities in the field of immunology.[1] "[I]n determining . . . whether the informational basis of an expert opinion is of a type reasonably relied upon by experts in the field, "[t]he proper inquiry is not what the court deems reliable, but what experts in the relevant discipline deem it to be." *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829, 853 (3rd Cir. 1990), *cert. denied*, 111 S. Ct. 1584 (1991) (citations omitted).[2] *See also id.* at 856-58; *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990) (reversing district court's grant of

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[1] Nor did Collagen contend that Dr. Spindler was not a competent medical expert.

[2] In *Paoli*, the Third Circuit reversed the district court's grant of summary judgment for defendants and held that the district court had failed to give reasons for excluding as unreliable the bulk of the expert testimony upon which the plaintiffs had relied to establish causation.

In the present case, it is unclear whether the district court found Dr. Spindler's affidavit inadmissible under Fed. R. Evid. 703, or whether the court found the affidavit admissible but concluded that the evidence was nonetheless insufficient to enable a jury to find causation. We need not resolve this ambiguity, however, because we conclude that the affidavit, taken on its own terms, established causation within a reasonable medical probability.

summary judgment for defendants; holding that the district court erred in failing to make a record-supported, factual finding that plaintiff's doctor relied upon data not regarded as reliable by experts in the field). Thus, the district court erred in concluding that Dr. Spindler's affidavit was insufficient to preclude summary judgment.

In closing, we note that *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991), and other Bendectin cases are distinguishable. In holding that the plaintiffs' evidence was unreliable, we and other circuits relied on specific factual findings as to what constituted generally accepted scientific methodology. *Id.* at 1130-31. *See also Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-13 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); *DeLuca*, 911 F.2d at 949-52 (discussing Bendectin case law from other circuits). In *Daubert*, we upheld summary judgment based on the large volume of unfavorable epidemiological studies establishing the absence of causation. 951 F.2d at 1129. *See also Brock*, 874 F.2d at 311. In that case, "[p]laintiffs' evidence of causation consisted primarily of expert opinion based on *in vitro* and *in vivo* animal tests, chemical structure analyses and the reanalysis of epidemiological studies." The defendant's evidence included "the affidavit of a physician and epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." *Daubert*, 951 F.2d at 1129. Here, Collagen presented no facts contradicting Dr. Spindler's testimony.

We hold:

1. The order granting the defendant's motion for summary judgment is reversed.

2. The order denying a new trial is mooted.

3. The order denying the plaintiffs leave to designate additional experts is vacated for reconsideration in light of the reversal of summary judgment.

REVERSED AND REMANDED.

Kennedy v. Collagen Corporation, No. 91-15597

KOZINSKI, Circuit Judge, dissenting:

> This is the heart of Dr. Spindler's affidavit:
>
> > The existence of anti-histone antibody is *suspect* [sic] that her immune system was triggered by an external source, which *could have been* the bovine collagen injections in her case. . . .
> >
> > Mrs. Kennedy's medical history, records and current laboratory results are *consistent with a temporal relationship* between her injections and her medical condition, including a severe adverse reaction to Defendant's product, with systemic immune disorders and deteriorating medical condition and clinical symptoms.

ER, Tab D, at 17 (emphasis added). Dr. Spindler also adds that "[m]ore recently, I have obtained and evaluated current laboratory rests results for her, which reveal a change in her ANA, and in the existence of anti-centromere antibody, previously not present." *Id.* Nowhere does Dr. Spindler explain the meaning of

"ANA" or "anticentromere antibody," nor does he intimate what either of these has to do with plaintiff's case against the defendant.

Dr. Spindler's affidavit is simply too indefinite to establish a "reasonable medical probability" that Kennedy's disorder is in any way linked with defendant's collagen treatments; it is rank speculation. Under the substantive law of California, which we are bound to apply, Kennedy was obligated to put forth "a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Kennedy's reliance upon this affidavit was insufficient to carry her summary judgment burden. I would therefore affirm the judgment against her.

Not for Publication

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CHARLOTTE KENNEDY; ROBERT L. KENNEDY, Plaintiffs-Appellants, v. COLLAGEN CORPORATION, Defendant-Appellee.	No. 91-15597 D.C. No. CV-89-02331-CAL **MEMORANDUM*** (Filed JUN 8 1992)

Appeal from the United States District Court for the Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted May 15, 1992
San Francisco, California

Before: FERGUSON, REINHARDT and KOZINSKI, Circuit Judges.

The district court did not err in ruling that Kennedy had failed to present sufficient evidence of causation to survive summary judgment. Under California law, Kennedy was required to prove causation "within a reasonable medical probability." *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal. App. 3d 396, 402 (1985). Her expert affidavits on causation, however, were either speculative,

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* This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

highly equivocal, or both. They thus provided an insufficient basis for a reasonable jury to find causation. *See id.* at 402-04; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986).

The district court's denial of Kennedy's motion for a new trial based on newly discovered evidence was not an abuse of discretion; Kennedy failed to show that she had exercised due diligence in searching for, but not discovering, the evidence earlier. *Contempo Metal Furniture Co. v. East Texas Motor Freight Lines, Inc.*, 661 F.2d 761, 766 (9th Cir. 1981).

Kennedy's challenge to the district court's refusal to designate Dr. Spindler as an expert for trial is moot, as there will be no trial.

AFFIRMED.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CHARLOTTE KENNEDY, et al., Plaintiffs,	)	
v.	)	No. C-89-2331-CAL
COLLAGEN CORPORATION, Defendant.	)	

ORDER ON MOTION FOR SUMMARY JUDGMENT

(Filed Dec. 10, 1990)

This is a product liability action, for injuries allegedly resulting to plaintiff Charlotte Kennedy from the use of defendant's product Zyderm Collagen Implant (ZCI). Mrs. Kennedy was treated with ZCI in 1982 as a cosmetic aid. By 1983 she developed systemic lupus erythematosus (SLE). She alleges that the SLE condition was caused by the ZCI. Her husband joins as a plaintiff, alleging loss of consortium.

I.

Defendant has moved for summary judgment, contending that there is no genuine issue of fact that plaintiff's SLE was caused by ZCI. As discussed below, defendant's motion is accompanied by evidence demonstrating the lack of a causal medical connection between ZCI and SLE.

Plaintiffs have opposed the motion, and their opposition includes a request for a continuance of the motion

under Rule 56(f) of the Federal Rules of Civil Procedure. Their opposition and request for continuance primarily concern the late offer by plaintiffs of evidence from Dr. Joseph Spindler. This court received Dr. Spindler's affidavit at the oral argument of the summary judgment motion. Plaintiffs also request leave of the court to designate Dr. Spindler as an additional expert witness for trial, since expert designations were concluded in October 1989.

II.

The primary issue in this case, and this motion, is medical causation. However, because of plaintiff's request for a continuance, the late filing of Dr. Spindler's affidavit, and the request to designate Dr. Spindler as an additional expert for trial, it is necessary to review the procedural history of the case.

The action was originally filed in February 1988, and was assigned to another judge of this court. When the case was reassigned to the undersigned judge, a status conference was held on August 11, 1989. At the status conference, the court was advised that all discovery had been concluded, except discovery regarding experts. This court then set the following deadlines: designation of experts by October 1989, a discovery cutoff of November 1989, and trial in early 1990. On September 15, 1989, on plaintiffs' motion, this court compelled that certain of defendant's medical files be produced to plaintiffs. In December 1989, plaintiffs' counsel withdrew from the case, and the trial date was therefore vacated. Several status conferences were held from January 1990 through

May 1990 to allow plaintiffs time to obtain new counsel and for new counsel to become familiar with the case. New counsel appeared in May 1990. A scheduling and status conference was held in June, 1990, at which time the court set the trial date for early 1991.

Defendant filed this motion for summary judgment in October 1990, and the hearing was held on November 16, 1990. The motion was then submitted for decision. The court has reviewed the moving and opposing papers, the record of the case, some subsequent communications sent to the court by plaintiffs and defendant, and the applicable legal authorities. The court concludes that plaintiffs' request for further accommodation must be denied, and summary judgment must be granted in favor of defendant.

III.

As stated, defendant contends that there is no genuine issue of material fact regarding the absence of causation between SLE and ZCI.

Plaintiffs' substantive claims are governed by California law. Under California law, in order to establish a prima facie case of product liability, plaintiffs must present sufficient evidence on the issue of medical causation. *Jones v. Ortho Pharmaceutical Corporation,* 209 Cal. Reptr. 456, 460 (1985): "The law is well settled that in a personal injury action causation must be proven within a reasonable medical probability based upon competent medical testimony. Mere possibility alone is insufficient to establish a prima facie case . . . "

Defendant's motion for summary judgment squarely raises the issue of whether a causal connection between ZCI and SLE can be demonstrated by plaintiffs within a reasonable medical probability and based upon competent medical testimony. The motion is accompanied by extracts from the depositions of physicians, previously designated as experts in this case. That testimony need not be discussed in detail. Suffice it to say that the motion and the testimony establish a prima facie case of the absence of medical causation.

IV.

Under the *Celotex* trilogy, *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242 (1986), the burden then shifts to plaintiffs to raise a genuine issue of material fact on causation. Plaintiffs' written opposition to the motion, filed before the question of Dr. Spindler's affidavit arose, was based upon the testimony of their designated expert Dr. Tuffanelli. However, his testimony is equivocal. He stated, "so in my mind, until I see some good honest published data in that area, I will remain *unconvinced* that it (ZCI) is *not* causing these diseases (SLE)." Even that equivocal opinion was undercut by testimony from his deposition. He stressed that a causal connection was merely "possible." He testified that no scientific data exists that examine the incidents of autoimmune diseases in persons who have used ZCI, and that it would therefore be difficult for any expert to base an opinion on information reasonably relied upon by any expert in the field. He did not express an opinion on the probability of

causation, and he indicated that causation theories are currently based upon speculation. This is not be evidence [sic] sufficient to meet the standard of Federal Rule of Evidence 703, and does not meet the standard of proof of medical causation required by California law. *Jones,* 209 Cal. Rptr. at 461.

Plaintiffs offered the affidavit of Dr. Spindler at the oral argument. And the court has reviewed and considered that affidavit. However, the court concludes that even Dr. Spindler's affidavit does not sustain plaintiffs' burden of establishing a genuine issue of material fact on causation. His opinion is based primarily on the temporal relationship between plaintiffs' use of ZCI and the development of her disease (*post hoc, ergo propter hoc*). The most that he can say is that the ZCI injections were "suspect," and that her condition "could have been" caused by taking ZCI. There do not appear to be any other laboratory tests of plaintiff, epidemiological evidence, or toxicological evidence upon which the opinion is based. Therefore, the court must conclude that even Dr. Spindler's affidavit does not create the genuine issue of material fact on medical causation necessary to defeat summary judgment.

V.

Plaintiffs seek leave to designate further experts, primarily Dr. Spindler, and to continue consideration of the motion for summary judgment. This request must be denied.

As the history of the case demonstrates, experts were designated over a year ago in October, 1989. And this

court was generous to plaintiffs in staying and continuing the proceedings from December 1989 to May 1990, when plaintiffs' new attorney entered the case. The change of counsel might arguably be a ground for granting plaintiffs further accommodation to designate new experts. However, no attempt to designate other experts new experts. However, no attempt to designate other experts was made between the date that plaintiffs' new counsel entered the case in May of this year and the date of the oral argument of the summary judgment motion.

IT IS THEREFORE ORDERED that summary judgment be granted in favor of defendant and against plaintiffs.

Dated: December 10, 1990.

/s/ Charles A. Legge
CHARLES A. LEGGE
UNITED STATES DISTRICT JUDGE

THE STATE OF TEXAS §

COUNTY OF HARRIS §

BEFORE ME, the undersigned authority, on this day personally appeared before me JOSEPH SPINDLER, M.D., who sworn to under oath before me, deposed and stated as follows:

"I am JOSEPH SPINDLER, M.D. I am over the age of 18 years, have never been convicted of a crime and am fully competent to make this affidavit. I am a medical physician licensed by the State of Texas specializing in rheumatology, and practice primarily in Houston, Texas. I have been licensed since 1973. A copy of my current curriculum vitae is attached hereto and incorporated herein for all purposes.

I have recently examined Charlotte Kennedy, Plaintiff, and have reviewed her extensive medical history and records. I have also obtained and evaluated numerous laboratory tests of Mrs. Kennedy and have reached a diagnosis and opinion as to her medical condition, past and present, and as to the causation of her condition.

Prior to her injections of Defendant's bovine collagen product, Mrs. Kennedy's records and history reflect an absence of any clinical course of lupus or autoimmune disease or any immunological condition. Her clinical course, however, dramatically and temporally deteriorated following her third injection of Defendant's bovine collagen product, including a positive ANA and anti-histone antibody, the latter of which is not usually seen in ideopathic lupus or immunological disorders. The existence of anti-histone antibody is suspect that her immune system was triggered by an external source, which could have been the bovine collagen injections in her case. Mrs. Kennedy was diagnosed as having systemic lupus erythematosus, an autoimmune disease, following her injections.

Mrs. Kennedy's medical history, records and current laboratory results are consistent with a temporal relationship between her injections and her medical condition, including a severe adverse reaction to Defendant's product, with systemic immune disorders and deteriorating medical condition and clinical symptoms. More recently, I have obtained and evaluated current laboratory test results for her, which reveal a change in her ANA, and in the existence of anticentromere antibody, previously not present.

Based on reasonable medical probability, Mrs. Kennedy suffered a definite adverse systemic immunological reaction to the bovine collagen injections, which injections triggered her systemic immunological injuries. This systemic immunological reaction has caused and was a substantial factor, if not the factor, in causing a changing immunological picture for Mrs. Kennedy; and with the temporal relationship, it appears the injections acted as a trigger in the development and progression of her evolving systemic-immune condition and disorders."

/s/ Joseph Spindler
JOSEPH SPINDLER, M.D.

SUBSCRIBED AND SWORN TO before me on this the 14th day of November, 1990, to certify which witness my hand and seal of office.

/s/ Kay Owens
NOTARY PUBLIC IN AND FOR
THE STATE OF TEXAS

MY COMMISSION EXPIRES:

Kay Owens
Notary Public in and for the
State of Texas
My Commission Expires
June 21, 1992

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CHARLOTTE KENNEDY; ROBERT L. KENNEDY,	)	No. 91-15597
Plaintiffs-Appellants,	)	D.C. No. CV-89-02331-CAL
v.	)	
COLLAGEN CORPORATION,	)	ORDER
Defendant-Appellee.	)	(Filed Dec. 16, 1992)

Before: FERGUSON, REINHARDT, and KOZINSKI, Circuit Judges

Judges Ferguson and Reinhardt voted to deny the petition for rehearing. Judge Kozinski voted to grant the petition for rehearing. Judges Reinhardt and Kozinski voted to deny the suggestion for rehearing en banc and Judge Ferguson so recommended.

The full court has been advised of the suggestion for en banc hearing and no active judge requested that a vote be taken on the suggestion for rehearing en banc. Fed. R. App. P. 35(b).

The petition for rehearing is denied and the suggestion for rehearing en banc is rejected.

FEDERAL RULES OF EVIDENCE

Rule 703. Bases of Opinion Testimony by Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987.)

UNITED STATES CODE TITLE 21. FOOD AND DRUGS CHAPTER 4 – FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBCHAPTER V – DRUGS AND DEVICES PART A – DRUGS AND DEVICES

§ 355. New Drugs

* * *

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests

show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the

drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

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CODE OF FEDERAL REGULATIONS

TITLE 21 – FOOD AND DRUGS

CHAPTER I – FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER D – DRUGS FOR HUMAN USE

PART 314 – APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG
SUBPART D – FDA ACTION ON APPLICATIONS AND ABBREVIATED APPLICATIONS

§ 314.126 Adequate and well-controlled studies.

(a) The purpose of conducting clinical investigations of a drug is to distinguish the effect of a drug from other influences, such as spontaneous change in the course of the disease, placebo effect, or biased observation. The characteristics described in paragraph (b) of this section have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation. The Food and Drug Administration considers these characteristics in determining whether an investigation is adequate and well-controlled for purposes of sections 505 and 507 of the act. Reports of adequate and well-controlled investigations provide the primary basis for determining whether there is "substantial evidence" to support the claims of effectiveness for new drugs and antibiotics. Therefore, the study report should provide sufficient details of study design, conduct, and analysis to

allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

(b) An adequate and well-controlled study has the following characteristics:

(1) There is a clear statement of the objectives of the investigation and a summary of the proposed or actual methods of analysis in the protocol for the study and in the report of its results. In addition, the protocol should contain a description of the proposed methods of analysis, and the study report should contain a description of the methods of analysis ultimately used. If the protocol does not contain a description of the proposed methods of analysis, the study report should describe how the methods used were selected.

(2) The study uses a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect. The protocol for the study and report of results should describe the study design precisely; for example, duration of treatment periods, whether treatments are parallel, sequential, or crossover, and whether the sample size is predetermined or based upon some interim analysis. Generally, the following types of control are recognized:

(i) Placebo concurrent control. The test drug is compared with an inactive preparation designed to resemble the test drug as far as possible. A placebo-controlled study may include additional treatment groups, such as an active treatment control or a dose-comparison control, and usually includes randomization and blinding of patients or investigators, or both.

(ii) Dose-comparison concurrent control. At least two doses of the drug are compared. A dose-comparison study may include additional treatment groups, such as placebo control or active control. Dose-comparison trials usually include randomization and blinding of patients or investigators, or both.

(iii) No treatment concurrent control. Where objective measurements of effectiveness are available and placebo effect is negligible, the test drug is compared with no treatment. No treatment concurrent control trials usually include randomization.

(iv) Active treatment concurrent control. The test drug is compared with known effective therapy; for example, where the condition treated is such that administration of placebo or no treatment would be contrary to the interest of the patient. An active treatment study may include additional treatment groups, however, such as a placebo control or a dose-comparison control. Active treatment trials usually include randomization and blinding of patients or investigators, or both. If the intent of the trial is to show similarity of the test and control drugs, the report of the study should assess the ability of the study to have detected a difference between treatments. Similarity of test drug and active control can mean either that both drugs were effective or that neither was effective. The analysis of the study should explain why the drugs should be considered effective in the study, for example, by reference to results in previous placebo-controlled studies of the active control drug.

(v) Historical control. The results of treatment with the test drug are compared with experience historically

derived from the adequately documented natural history of the disease or condition, or from the results of active treatment, in comparable patients or populations. Because historical control populations usually cannot be as well assessed with respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies of diseases with high and predictable mortality (for example, certain malignancies) and studies in which the effect of the drug is self-evident (general anesthetics, drug metabolism).

(3) The method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis is directed.

(4) The method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables such as age, sex, severity of disease, duration of disease, and use of drugs or therapy other than the test drug. The protocol for the study and the report of its results should describe how subjects were assigned to groups. Ordinarily, in a concurrently controlled study, assignment is by randomization, with or without stratification.

(5) Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding.

(6) The methods of assessment of subjects' response are well-defined and reliable. The protocol for the study and the report of results should explain the variables measured, the methods of observation, and criteria used to assess response.

(7) There is an analysis of the results of the study adequate to assess the effects of the drug. The report of the study should describe the results and the analytic methods used to evaluate them, including any appropriate statistical methods. The analysis should assess, among other things, the comparability of test and control groups with respect to pertinent variables, and the effects of any interim data analyses performed.

(c) The Director of the Center for Drug Evaluation and Research may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific clinical investigation, either prior to the investigation or in the evaluation of a completed study. A petition for a waiver is required to set forth clearly and concisely the specific criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be, or have been employed, and what results have been obtained. The petition is also required to state why the clinical investigations so conducted will yield, or have yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(d) For an investigation to be considered adequate for approval of a new drug, it is required that the test drug be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(e) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

(Collection of information requirements approved by the Office of Management and Budget under number 0910-0001.)

[50 FR 21238, May 23, 1985; 55 FR 11580, March 29, 1990]

CHAPTER I – FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Editorial Note: The Food and Drug Administration (FDA) published a document at 55 FR 276, Jan. 4, 1990 establishing January 1, 1993, as its new uniform compliance date with all FDA final food labeling regulations that are published in the Federal Register after January 1, 1990, and before January 1, 1992.

PART 314 – APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 376).

Source: 39 FR 11718, Mar. 29, 1974; 50 FR 7493, Feb. 22, 1985; 50 FR 21238, May 23, 1985; 54 FR 39636, Sept. 27, 1989; 55 FR 37322, Sept. 11, 1990, unless otherwise noted.

SUBPART D – FDA ACTION ON APPLICATIONS AND ABBREVIATED APPLICATIONS

Source: 57 FR 17983, April 28, 1992, unless otherwise noted.